

Attorney Docket No. 40128/02301 (08240-173)

**REMARKS**

**I. INTRODUCTION**

Claims 4 - 8, 10, 15 - 32, 36, 37, 39, 40, and 42 - 45 are pending in the present application. In light of the following remarks, Applicants respectfully submit that all presently pending claims are in condition for allowance.

**II. THE 35 U.S.C. § 103(a) REJECTIONS SHOULD BE WITHDRAWN**

Claims 36 and 37 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,261,601 to Ross et al. ("Ross") in view of U.S. Patent No. 5,630,796 to Bellhouse et al. ("Bellhouse"). 10/8/09 Office Action, p. 2.

Claim 36 recites, "[a] method for needleless injection of a liquid substance into a target biological tissue, the method comprising: generating droplets of the liquid substance; accelerating the droplets of the liquid substance, at a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue; and *directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue*; wherein generating the droplets of the liquid substance comprises injecting a pressurized gas from a pressurized source into a reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through at least one micro-orifice of a perforated membrane to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets."

Ross describes a dispensing apparatus such as a hand-held dispensing apparatus for oral inhalation. Ross, Abstract. The dispensing apparatus comprises a chamber for containing a liquid to be dispensed, a perforated membrane defining a front wall of the chamber and a vibrating transducer for vibrating either the perforated membrane or a rear wall of the chamber so as to eject droplets of the liquid through the holes of the perforated membrane. *Id.*

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Bellhouse discloses a method for delivering powder transdermally with a needleless injector having a membrane that is ruptured by pressure, from an energy mechanism such as, for example, from a gas cartridge. *Bellhouse*, Abstract.

The Examiner contends that it would have been obvious to one of ordinary skill in the art to modify the device of Ross with the energy mechanism of Bellhouse to use gas pressure to move the liquid substance through the perforated membrane. *10/8/09 Office Action*, p. 3: Applicants respectfully disagree. Specifically, Ross discloses "...this droplet size being suitable for delivery of atomized products to the lungs of a patient." *Ross* at col. 7, ll. 13 – 15. Ross clearly describes that a delivery of the atomized products is made by *oral inhalation* rather than by injection, as disclosed in the recited claim. Thus, it is respectfully submitted that Ross never intends to have the droplets injected into the lungs of a patient, but rather intends for the droplets to be of an adequate size to reach the lungs of a patient through inhalation. *Id.* at col. 7, ll. 34 – 35.

The Examiner further contends, however, that the "velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue" of claim 36 is in itself met by Ross since Ross also injects the droplets in the target tissue when the droplets are inhaled into the lungs of a patient. *10/8/09 Office Action*, p. 6. Applicants respectfully disagree. Inhalation of the droplets of liquid substance by the patient will deposit the droplets onto the lungs' tissue. The droplets will then be absorbed by the patient's lungs through a natural process. It is respectfully submitted that it would be clear to one of ordinary skill in the art that inhalation will not give to the droplets a "velocity sufficiently high for injection of the droplets in the lungs tissue," as recited in claim 36.

The Examiner also contends that an object of Ross is to have a vibrating perforate membrane having enhanced performance in which the rate at which liquid is dispensed is improved and that introducing a pressurized gas source as taught by Bellhouse would be likely to meet this objective. *10/8/09 Office Action*, p. 6. It is respectfully submitted that,

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in Ross, improving the rate at which the liquid is dispensed is only relevant to the production of droplets for inhalation purposes, not to the production of droplets for having "a velocity sufficiently high to inject the droplets of liquid substance into the target biological tissue." It is respectfully submitted that using a vibrating transducer cannot produce such a high velocity. In addition, in Ross, enhancing performance of the vibrating perforated member is irrelevant to the combination of Ross and Bellhouse since, if combined as suggested by the Examiner, the droplets would be produced by the pressurized gas source such that the vibrations would no longer be used for that purpose. Therefore, it is respectfully submitted that combining Bellhouse with Ross as suggested by the Examiner would destroy the utility of the vibrations transmitted to the perforated member to produce atomized droplets suitable for inhalation. Thus, the purpose of Ross would be destroyed.

Furthermore, it is respectfully submitted that it is unclear how the Examiner would modify Ross in view of Bellhouse since the basic purpose of the Ross device is completely different from that of the claimed invention. It is respectfully submitted that modifying the device of Ross to incorporate a gas cartridge as taught by Bellhouse would either destroy the purpose of Ross' inhalation device, as discussed above, or differ from the claimed invention.

Specifically, mounting a cartridge similar to Bellhouse to Ross' inhalation device would have the following effect. In Ross, a vibrating transducer produces, through a perforated membrane, low-velocity droplets for the purpose of inhalation by the patient. Ross teaches no rupture of this perforated membrane. In contrast, Bellhouse teaches the rupture of the membrane and, therefore, if the teaching of Bellhouse is applied to Ross without inventive modification, the membrane of Ross would rupture and no droplets would be produced through the perforated membrane. Consequently, the released gas could not be used to accelerate droplets that do not exist. Obviously, such a combination would not, in separate steps, produce and accelerate droplets in a manner suitable for injection within the patient's biological tissue. In the same manner, such a

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combination would not be capable of producing low-velocity droplets suitable for inhalation.

On the other hand, should a reduced pressure cartridge (which is not taught by Bellhouse and would therefore require further modification and adaptation to the cartridge) be mounted to Ross' device to render the atomized mist suitable for oral inhalation, the resulting device would be different from the presently claimed invention since the claimed invention, as claimed in claim 36, requires the acceleration of the droplets of the liquid substance at a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue.

Therefore, Applicants respectfully submit that Ross and Bellhouse, taken alone or in combination, fail to disclose or suggest *"directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue,"* as recited in claim 36. Thus, it is respectfully submitted that claim 36 is not rendered obvious by Ross in view of Bellhouse and that the rejection of this claim should be withdrawn.

Claim 37 recites limitations that are substantially similar to the limitations of claim 36. For at least the same reasons as discussed above in regard to claim 36, it is respectfully submitted that claim 37 is also allowable and that the rejection of this claim should be withdrawn.

Claims 4 – 8, 10, 15 – 32, 39 and 40 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ross in view of Bellhouse. *10/8/09 Office Action*, p. 3.

Claim 39 recites "[a] method for needleless injection of a liquid substance into a target biological tissue, the method comprising: generating a high velocity jet of gas; generating droplets of the liquid substance; supplying and conveying the droplets of the liquid substance into the high velocity jet of gas; and guiding the high velocity jet of gas through a channel toward a surface of the target biological tissue for injecting the

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conveyed droplets of the liquid substance into the target biological tissue; wherein generating the droplets of the liquid substance comprises: containing the liquid substance into a reservoir; interposing a perforated membrane between the reservoir and the channel in such a manner *that the flow of the high velocity jet of gas is guided along a face of the perforated membrane* on a side of the perforated membrane opposite to the reservoir of the liquid substance; and pressurizing the reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through the perforated membrane to thereby *produce a jet of the liquid substance that transforms into a stream of the droplets supplied within the high velocity jet of gas laterally of the direction of the flow of said high velocity jet of gas.*"

As discussed above in regard to claim 36, it is respectfully submitted that modifying Ross in view of Bellhouse is either improper or does not render the claimed invention obvious.

It is respectfully submitted that there would be no basis to combine the references of Ross and Bellhouse. Contrary to the Examiner's assertions, Ross does not describe a device and method for a needleless injection of a liquid substance. As indicated in the foregoing comments, the velocity of the droplets generated by the transducer of Ross is not sufficiently high for the droplets to penetrate a surface of a biological tissue. This is due to the fact that the dispensing apparatus is used to generate droplets which are subsequently inhaled through the mouth; no inhalation would be possible if the droplets would penetrate the mouth's biological tissues by being injected therein. More specifically, there would be no basis to combine a dispensing apparatus as taught by Ross to produce a mist of droplets suitable for inhalation by a patient with a needleless transdermal power injector as taught by Bellhouse. It is believed that one of ordinary skill in the art would not consider an apparatus for producing a mist of droplets for inhalation when trying to construct a device for injecting droplets of a liquid substance into a biological tissue.

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The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the pressure source of Ross with the pressurized gas of Bellhouse for generating enough pressure to create an atomized spray of liquid droplets. *10/8/09 Office Action*, p. 4. If the pressure source of Ross is modified to include the pressurized gas source of Bellhouse to create an atomized spray of liquid droplets, as suggested by the Examiner, it is understood that the pressurized gas of Bellhouse will be supplied into the chamber 3 of Ross containing liquid 4 to be dispensed. The pressurized gas would then force the liquid and gas through the perforations of the membrane to produce, as suggested by the Examiner, droplets. Since the liquid and pressurized gas flow through the perforations of the membrane 13, it is not possible with such a construction to interpose the perforated membrane between the reservoir of liquid and the channel in such a manner that the flow of the high velocity jet of gas is guided along a face of the perforated membrane on a side of the perforated membrane opposite to the reservoir of the liquid. In the proposed construction, the channel would be perpendicular to said side of the perforated membrane whereby the jet of gas flowing in the channel cannot flow *"along a face of the perforated membrane"* to produce *"a jet of the liquid substance that transforms into a stream of the droplets supplied within the high velocity jet of gas laterally of the direction of the flow said high velocity jet of gas,"* as recited in claim 39.

In addition, it is respectfully submitted that the Examiner's statement that "the jet of gas in Bellhouse is guided along a face of the perforated membrane on a side opposite to the liquid reservoir" is not possible. In Bellhouse, when gas pressure is released and reaches a given level, the membranes 33 and 34 of the capsule 28 of particulate material burst to allow passage of the pressurized gas. Initially, the membranes 33 and 34 are perpendicular to the flow of gas and after bursting of the membranes there no longer exists any reservoir that could contain particulate material. Accordingly, the jet of gas of cannot be guided along a face of a perforated membrane on a side opposite to a liquid reservoir to supply a jet of the liquid substance that transforms into a stream of the droplets within the high velocity jet of gas laterally of the direction of the flow said high velocity jet of gas.

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Thus, it is respectfully submitted that claim 39 is not rendered obvious by Ross in view of Bellhouse and that the rejection of this claim should be withdrawn. Because claims 4 – 8 and 10 depend from and include all of the limitations of claim 39, it is respectfully submitted that these claims are also allowable.

Claim 40 recites limitations that are substantially similar to the limitations of claim 39. For at least the same reasons as discussed above in regard to claim 39, it is respectfully submitted that claim 40 is not rendered obvious by Ross in view of Bellhouse. Because claims 15 – 32 depend from and include all of the limitations of claim 40, it is respectfully submitted that these claims are also allowable.

Claims 42 – 45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ross in view of U.S. Patent No. 6,689,095 to Garitano et al. (“Garitano”). *10/8/09 Office Action*, p. 5.

Claim 42 recites “[a] method for needleless injection of a liquid substance into a target biological tissue, the method comprising: generating droplets of the liquid substance; accelerating the droplets of the liquid substance, at a velocity sufficiently high *to inject the droplets of the liquid substance into the target biological tissue*; and directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue; wherein generating the droplets of the liquid substance comprises: supplying pressurized gas to a gas-tight chamber; applying, by means of the pressurized gas in the gas-tight chamber, a pressure to a slidable piston interposed between the gas-tight chamber and a reservoir of the liquid substance to be injected;

compressing the liquid substance in the liquid reservoir by means of the pressure applied to the slidable piston to force the liquid substance through at least one micro-orifice of a perforated membrane to thereby produce a jet of the liquid substance, *wherein the jet of the liquid substance transforms into a stream of the droplets.*”

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Garitano discloses a permanent makeup and tattoo device using a compressed gas actuated piston as an energy mechanism.

The Examiner contends that it would have been obvious to a person of ordinary skill in the art to have modified the pressure source of Ross with the energy mechanism of Garitano to control the liquid injection. *10/8/09 Office Action*, p. 6. Applicants respectfully submit that Ross is not suitable as a primary reference, at least since it discloses an inhalation device. As previously mentioned with regard to Bellhouse, even if Ross' inhalation device was modified with the piston containing energy mechanism of Garitano, the resulting device would either destroy the utility of Ross or lack the power to inject the droplets of the liquid substance as seen in the claimed invention. Furthermore, Garitano produces and injects one drop at a time ("a microdroplet") and fails to teach production of "*a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets,*" as recited in claim 42. *Garitano*, col. 14, ll. 47-50. Accordingly, it is respectfully submitted that there is no incentive for one of ordinary skill in the art to use the teachings of Garitano to produce streams of droplets while increasing the velocity of these droplets for injection in a target biological tissue.

Thus, it is respectfully submitted that claim 42 is not rendered obvious by Ross in view of Garitano and that the rejection of this claim should be withdrawn. Similarly, it is respectfully submitted that claims 43 – 45, which include limitations substantially similar to the limitations of claim 42, are also allowable.



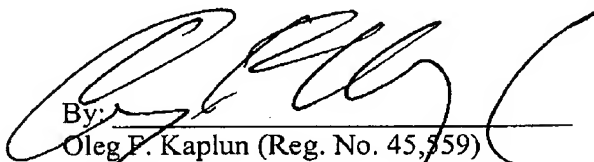
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**CONCLUSION**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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